Docket No.: 62526US(50221)
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Mario Clerici et al.

Application No.: 10/516,421 Confirmation No.: 5505

Filed: June 30, 2005 Art Unit: 1634

For: TREATMENT WITH CYTOKINES FOR ALZHEIMER'S DISEASE Examiner: S. L. Bausch

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being transmitted by facsimile to (571) 273-8300 at the U.S. Patent and Trademark Office on September 11, 2007.

By: Donna Merryman
Donna Merryman

RESPONSE TO RESTRICTION REQUIREMENT

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Claims 1-20 are pending in the instant application and are subject to restriction.

The Office Action, mailed April 11, 2007, on page 2, requires restriction to one of the following groups under PCT Rule 13.1:

Group I, claim(s) 1-4, which are directed to methods of determining a predisposition to Alzheimer's disease, autoimmune disease or neurodegenerative disease;

Group II, claim(s) 10, which are directed to methods of treating a disease by augmenting the function of a gene;

Group III, claim(s) 11, which are directed to a nucleic acid;

525344

Group IV, claim(s) 12, which are directed to the use of a nucleic acid for modulating allelic polymorphisms.

Group V, claim(s) 13, which are directed to the use of a nucleic acid for modulating or preventing Alzheimer's disease;

Group VI, claim(s) 17, drawn to use of cytokine.

Group VII, claim(s) 18, which are directed to methods of treating disease using genetic therapy and decreasing function of a gene;

Group VIII, claim(s) 19-20, which are directed to methods of treating disease using pharmacological intervention and decreasing function of a gene; and

the Office has further required the election of specific allelic variants.

As an initial matter, Applicants wish to thank S.P.E. Ram Shukla for speaking with them on August 10, 2007, and granting them an opportunity to clarify certain aspects of the Restriction Requirement. In accordance with this discussion, and in response to the restriction requirement, Applicants hereby provisionally elect the invention of Group I, claims 1-4, for continued examination; in addition, Applicants provisionally elect the following allelic variants: for the gene encoding IL-10, Applicants provisionally elect the G to A mutation at -1082, the T to C mutation at –819, and the A to C at –592; for the gene encoding IL-6, Applicants provisionally elect the -174C allele; for the gene encoding IL-1, Applicants provisionally elect the –1082A allele; and for the gene encoding ApoE, Applicants provisionally elect Apo-E 4 carrier status. For the reasons detailed below, Applicants respectfully traverse the requirements for restriction and election, and submit that the requirements are improper.

First, Applicants assert that the subject matter of these groups represent different embodiments of a single inventive concept for which a single patent should issue. The pending claims represent an intricate web of knowledge, continuity of effort, and consequences of a single invention, which merit examination of all of these claims in a single application. More

particularly, a single, searchable, unifying aspect links all of the claims. This single, searchable, unifying aspect comprises the identification of allelic polymorphisms related to Alzheimer's disease.

Second, Applicants submit that a sufficient search and examination with respect to the subject matter of all claims can be made without serious burden. As the M.P.E.P. states:

> If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. M.P.E.P. § 803 (8th ed., Rev. No. 2, May 2004).

That is, even if the above-enumerated groups of claims are drawn to distinct inventions, the Examiner must still examine the entire application on the merits because doing so will not result in a serious burden. This is especially true given the robust and extensive computerized search engines and databases at the Examiner's disposal.

Furthermore, Applicants note that the Examiner cites Shin et al., "Genetic Restriciton of HIV-1 Pathogenesis to AIDS by Promoter Alleles of IL-10," PNAS 97:14467-14472, 2000 (hereinafter "Shin"), as destroying the unity of invention of the present claims. The Office alleges that the present invention does not constitute a special technical feature as defined by PCT Rule 13.2 over Shin. Applicants respectfully disagree. Shin relates to the use of various polymorphisms to identify individuals at increased risk for HIV infection. Shin fails to describe the analysis of a DNA sample from a subject to determine the existence of or a predisposition to Alzheimer's disease. HIV is an infectious disease. In contrast, Alzheimer's disease is a disease of aging that is unrelated to HIV infection. Applicants" invention is, therefore, plainly distinguishable from the work of Shin, and constitutes a contribution over the art cited by the Examiner.

Accordingly, it is respectfully requested that the restriction requirement be reconsidered and the elected claims of Group I be rejoined with those of Groups II-VIII.

Application No.: 10/516,421 Docket No.: 62526(50221)
Response dated September 11, 2007
Response to Office Action mailed April 11, 2007

Applicants believe no additional fee is due with this response. However, if any additional fee is due, please charge our Deposit Account No. 04-1105.

Dated: September 11, 2007

Respectfully submitted,

By _____

Melissa Hunter-Ensor, Ph.D.
Registration No.: 55,289
EDWARDS ANGELL PALMER & DODGE LLP
P.O. Box 55874
Boston, Massachusetts 02205
(617) 517-5580
Attorneys/Agents For Applicant